



INSTRUCTIONS FOR USE

Read these instructions for use carefully before you start using evaQwax. Keep these instructions for use, you may need to read it again. If you require additional information or have any further questions, ask your doctor, pharmacist, nurse or other healthcare professional.

What evaQwax ear spray is and what it is used for:

evaQwax ear spray is a cerumenolytic solution scientifically formulated to soften and dissolve earwax from the external ear canal.

It can be administered to:

- Remove impacted earwax.
- Prevent excessive accumulation of earwax, as a secondary prevention, to reduce future episodes.
- Ease the irrigation or earwax manual removal procedures, improving the patient tolerability.

The functional ingredient is hydrogen peroxide. This works by releasing oxygen, which breaks up the earwax into smaller fragments that are easier to eliminate. In addition to hydrogen peroxide, evaQwax contains a buffer that acts as a stabiliser to maintain a slightly acidic pH, consistent with the physiology of the external ear canal. evaQwax does not contain oils.

evaQwax comes in a 45 ml bottle with an ear dispensing device.

Who can use evaQwax ear spray:

evaQwax is suitable for use in adults and children from 3 years old.

In the case of children, the product must be administered by a parent, caregiver, or healthcare professional. Children should not self-administer this product. In individuals with physical or mental impairments, the product should only be used under the supervision of a caregiver or healthcare professional to ensure correct and safe application.

Do not use evaQwax ear spray if:

- you are allergic to any of the ingredients;
- you have, or suspect that you may have, an ear infection (can present with pain, fever, discharge);
- you have, or suspect that you may have, a perforated eardrum;
- you have tympanostomy (ventilation) tubes; or
- you have had a recent ear surgery unless specifically cleared by the doctor.

Using other products or medicine with evaQwax ear spray:

evaQwax will not interact with any other product or medicine that you may be taking.

However, do not use any other ear product during the course of treatment.

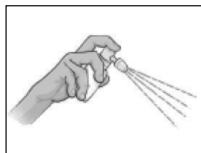
In case of doubt ask your healthcare professional.

How to use evaQwax ear spray:

evaQwax is applied using the ear dispensing device specially designed for use in the external ear canal as shown in the drawings below.

If you use hearing aids, you must remove them before using evaQwax.

Before using evaQwax, assemble the ear dispensing device with the bottle by exerting slight pressure.



1. Before each use, spray repeatedly in the air until the liquid comes out.



2. Tilt the head so the affected ear faces upward and gently pull the ear backwards.



3. Place the ear dispensing device in the external ear canal, with particular care in children below 9 years, and press it (to know the dosage, see the next section **How often to use evaQwax ear spray**). Keep the head tilted for about 2 minutes. Wipe away any surplus running from the ear with a tissue.



4. Turn the head in the opposite direction to allow the liquid to drain and dry holding a clean tissue.



5. Clean the ear dispensing device with water and dry it. Keep it for future applications.

How often to use evaQwax ear spray:

Follow the recommendations in this table, unless your healthcare professional recommends a different schedule.

The schedule of administration varies if evaQwax ear spray is used to treat an already formed earwax impaction, or if you want to prevent its accumulation. Children from 3 to 9 years old have a smaller external ear canal and they need a smaller quantity of liquid.

		Recommended treatment regimen	
Age	Dosage (No. of sprays)	Earwax impaction	Prevention of excessive accumulation of earwax
Children from 3 to 9 years old:	Press 2 or 3 times	Twice a day for 3 to 5 days	If you need earwax removal procedure twice per year, use evaQwax twice a week.
Adults and children over 9 years old:	Press 4 or 5 times		If you need earwax removal procedure three times per year, use evaQwax three times per week, and so on.

If you used too much evaQwax, simply wipe away any surplus running from the ear with a tissue. Continue to use the next dose of evaQwax as per the recommended regimen.

Possible side effects:

Just because a side effect is stated here, it does not mean that all people using this product will experience that or any other side effect.

It has been reported that cerumenolytic solutions may cause discomfort, pain, transient hearing loss (due to the liquid presence in the ear canal), dizziness, allergic reactions, potential external otitis, and skin irritation.

On rare occasions, it has been reported that it can cause itching.

The release of oxygen may cause a temporary bubbling sensation.

In case of excessive pain, discomfort or loss of hearing is noticed, as well as any other possible side effects not mentioned before, you should stop using evaQwax and seek medical attention.

Warnings and precautions:

USE IN THE EAR ONLY.

Do not share evaQwax with any other person.

Consult your healthcare professional if the problem worsens or persists.

In case of contact with eyes, rinse immediately with plenty of water.

Do not swallow.

In case of accidental ingestion of the product, seek immediate medical assistance.

This product may stain clothing.

Do not insert foreign objects such as cotton buds or bobby pins into the ear canal.

Do not use if the package is damaged.

If you are pregnant or breastfeeding, ask your healthcare professional for advice before using evaQwax. There is no experience regarding the use of evaQwax during pregnancy and breastfeeding. Therefore, evaQwax should not be used if you are pregnant or breastfeeding unless recommended by your healthcare professional.

Any serious incident that has occurred in relation to the device should be reported to the distributor, and this immediately to the manufacturer who will accordingly report to the competent authority.

How to store evaQwax ear spray:

Keep out of reach of children.

Store below 30 °C.

Keep the bottle inside the carton for proper conservation.

Store in an upright position.

Do not refill the container.

Do not freeze.

Do not use after the expiry date printed on the carton and bottle, even if the product has not been used.

Use within 12 months after opening.

Return all unused product to your pharmacist.

Do not dispose of unused product in drains or sewerage systems (e.g. toilets).

Composition:

Hydrogen peroxide 3 %, phosphate buffer 0,815 % (dihydrogen sodium phosphate, hydrogen disodium phosphate), water.

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